Office of Pesticide Programs

FIFRA Laboratory Environmental Check Sample Support Program

Draft

Statement of Work

PR-HQ-04-11892

Division

CONTENTS

DRAFT

FIFRA Laboratory Environmental Check Sample Support Program Statement of Work

– BACKGROUND:

The Environmental Protection Agency (EPA), Office of Pesticide Programs (OPP) Biological and Economic Analysis Division (BEAD) has provided an environmental check sample/proficiency sample program for state FIFRA laboratories. This program was conducted at the request of the states to assist in internal quality assurance programs and in obtaining and maintaining accreditation with various accrediting bodies [e.g., International Organization for Standardization (ISO)]. State FIFRA laboratories are often called upon to analyze soil or vegetative samples for the presence of pesticides and, therefore, require technical assistance to keep current with the methodologies in these areas. The goal of the check sample program is to enable states to verify accuracy and reliability of data and laboratory performance.

– GENERAL REQUIREMENTS:

The requirements contained in this statement of work are performance-based, focusing on the Agency's performance objectives. The contractor shall be responsible for determining the most effective means by which these requirements will be fulfilled. This performance-based requirement represents a challenge to the contractor to design and develop innovative processes and systems to meet or exceed the performance objectives, measures, and standards described below. Typical areas that are measured include cost control, timeliness and completeness of deliverables, problem resolution, business relations, quality of work performed, and whether or not the deliverable assists the Agency in meeting its objectives and goals as identified in the tasks. The Agency will monitor the contractor's performance in accordance with its own Quality Management Plan (QMP) and Quality Assurance Project Plan (QAPP) prepared in the association with the Project Plan in Task 1. The QMP and the QAPP will conform with all requirements of EPA QA/R-2 and -R5 [www.epa.gov/quality/qa_docs.html].

In cases where performance objectives and minimum acceptable quality levels (AQLs) are not being met, the contractor will make every effort to immediately correct the problem. If the

problem is systemic, the contractor will submit a plan of corrective action to the Project Officer (PO) or Work Assignment Manager (WAM).

The required services will be specified through Work Assignments issued by the Contracting Officer (CO) and technically managed by the PO or APO and Work Assignment Manager (WAM). The tasks within this contract are: 1) Development of a check sample/proficiency sample test program for State FIFRA laboratories with a final accreditation by the American Association of Laboratory Accreditation (A2LA) or similar accreditation body; 2) Implementation of the EPA approved check sample/proficiency sample test program for State FIFRA laboratories; 3) Assistance to perform a feasibility study to compile information for the subsequent development and operation of a secure web-based analysis and reporting system.

TASKS

Task 1: Development a Five-Year Check Sample/Proficiency Sample Program Plan for State FIFRA Laboratories

The Contractor shall develop a Plan for implementing and conducting a check sample/proficiency sample program to support the quality assurance (QA) work at state laboratories. The Plan shall include the provision to eventually conduct two check sample/ proficiency sample exercises that will be used by state laboratories doing work in support of EPA FIFRA programs each year. The Plan will include up to 52 state FIFRA laboratories in the pesticide environmental residue area. The established exercises must provide pesticide samples in foliage/grass or soil matrices. The designated matrices shall be spiked with levels of preselected pesticide(s) and shall be pre-analyzed to verify stability of the pesticide(s) and homogeneity/uniformity of the spiking level(s) throughout the sample matrix. Guidance for this Plan shall come from the PO, APO, or WAM, EPA experienced-based approaches and protocols, initial assessments of state laboratory requirements, suggestions from the State AAPCO Steering Committee, the contractor's successful experience-based approaches, and widely accepted approaches supported by the American Chemical Society (ACS), the Association of Official Analytical Chemists (AOAC) International, and other standard-setting organizations [e.g., ISO Guide 43-1 (1997)]. [An excellent guideline to proficiency testing requirements can be found in the technical communications: *International Harmonized Protocol for Proficiency Testing of (Chemical) Analytical Laboratories, Journal of the AOAC International, 1993, Volume 76 (4): 926-940].*

The Plan must be approved by the PO, APO, or WAM. The Plan shall address methods and procedures for:

- delivering a Quality Management Plan (QMP),

- preparing a Quality Assurance Project Plan (QAPP),
- obtaining certified standard materials,
- confirming identities of the analytes,
- preparing and verifying the concentrations of standards and spiking solutions,
- distribution of the standards or solutions,
- reporting of results from participating laboratories,
- statistical methods and criteria for evaluating and reporting these results,
- documentation of all information,
- safe handling and shipping of reference and spiking materials,
- stepwise procedures for the spiking and preparation of homogeneous matrices and insurance of the stability of the matrices for the duration of the study.

Initial assessments and determination of specific laboratory requirements shall be accomplished through teleconferences with the AAPCO Steering Committee, attendance at State-Federal meetings, and on-site visits to selected laboratories. The Contractor shall incorporate this information into the Plan. The Contractor, in consultation with the PO, APO, or WAM, shall develop a schedule for conducting these exercises and append it to the Plan.

Upon completion of the program plan, the contractor must acquire A2LA accreditation of the FIFRA check/proficiency sample program within six months after the program plan has been developed.

The Contractor shall provide reports to each participating State on their results from these exercises including analytical methodology, in-house QA/QC, and statistical evaluations. The contractor will tabulate, calculate, and distribute reports from all sample exercises, within 21 days of the close of each exercise, to the participating laboratories and EPA-BEAD. The reports will include summary data that includes numerical results from all participants, reported in a coded format and will also provide each participating laboratory, and EPA-BEAD, a report showing the true value, the z-score, and the laboratory result for each analyte reported by the laboratory. The participating laboratories will have established protocols for evaluating the results. The contractor will present the data and z-scores but will make no judgement on acceptability. The contractor will also provide:

- a report of the reference laboratory results for applicable analytes,
- a report of the results from participating laboratories,
- statistical methods and criteria for evaluating and reporting these results,
- documentation of all information.

Work Approach

In gathering information, conducting interviews, or performing research, the contractor shall identify himself/herself as a contractor to EPA, not an EPA employee.

The contractor shall not interpret EPA policy on behalf of EPA nor make decisions on matters of policy, regulation, or statute.

DELIVERABLES:

1) Prepare a draft QMP, QAAP, and Check Sample/Proficiency Sample Program Plan to be received by the PO, APO, or WAM within the time frame specified in the Work Assignment. EPA will provide comments on these draft documents within ten working days of receipt.

2) Upon receipt of EPA comments a Final QMP, QAAP, and Check Sample/Proficiency Sample Program Plan to be received by the PO, APO, or WAM within the time frame specified in the Work Assignment.

ACCEPTANCE CRITERIA:

The draft and final plans shall be submitted within the time frame specified in the Work Assignment.

Task 2: Conduct a Five-Year Check Sample/Proficiency Sample Program for State FIFRA Laboratories

Two sample sets per year will be provided by the contractor. One set in the fall of the calendar year and the other in the spring. Up to 52 laboratories may participate in this program. In the first year of the program, and every other year thereafter, the sample matrix will be soil. In the second year of the program, and every other year thereafter, the sample matrix will be vegetation.

A sample set will consist of five separate samples of the same identical matrix. One of the samples will be designated as a blank and it will be made known as such to the laboratories. Each of the other four samples will contain one (1) to four (4) of the listed pesticides from the analyte categories (Appendix 1). Only one analyte category will be contained in a given sample. Standards for preparing the stock solutions shall be obtained from the EPA Pesticide Standards Repository.

An unfortified sample (i.e., blank) of 100 grams must be provided as well as four (4) samples of 20 gram each fortified with analyte material. Prior to being used for fortification, the soil and vegetation shall be analyzed for pesticides in Categories 1, 2, 3 and 4 (see Appendix 1). Soil will be heat treated and sufficiently mixed to be of a consistent particle size, and characterized for possible cross-contamination. Enough soil shall be prepared to last for all five years that soil will be used in the study. In the case of the vegetation, the samples will be freeze dried and not

heated and tested to determine sufficient matrix stability.

The samples will be contained in wide mouth EPA 200 series amber jars, certified to meet EPA analyte specifications for pesticide/PCB analyses. All containers will be lined with Teflon fluorocarbon resin.

Assigned values for the analytes will be determined by the contractor in a manner consistent with ISO Guide 43-1 (1997) and ISO/IEC 17025 (1999). ISO Guide 43 states that "When bulk material is prepared for a proficiency test, it should be sufficiently homogeneous for each test parameter so that all laboratories will receive test items that do not differ significantly in the parameters to be measured." Homogeneity testing will be performed on the test materials for each round using a sufficient number and variety of analytes to represent the various classes and types of pesticides contained in the round. There will be no fewer than 3 and no more than 10 samples tested for homogeneity. The failure of one test material to meet the requirements of homogeneity will result in the failure of the batch to be released for distribution. The preparation of a new batch of test material that meets homogeneity requirements will be obligatory.

Homogeneity testing will occur on an annual basis for each of the analyte categories to be used in the sample sets for that calendar year. Samples will be selected at random, extracted in total, and analyzed. The samples will be analyzed using an analytical method utilized for FIFRA samples. The mean values and target CV of 10% derived from the homogeneity testing will be provided.

Stability testing will be conducted to provide evidence that the samples are sufficiently stable and will not undergo any significant change throughout the length of the proficiency testing. Stability testing will be performed prior to release to release of the check samples to the participants for the analytes selected for use in the two sample sets. The testing will include sub-sampling during a six week period with sample numbers to assess significant change necessary to indicate stability.

Prior to the shipment of the first sample set, a trial exercise will be conducted to ensure that the program is performing properly. The contractor will prepare the sample set (a blank sample and one fortified sample). It is strongly recommended that a minimum of two reference laboratories conduct the trial and the results of the exercise be used to determine if the program is satisfactory for FIFRA check/proficiency exercises.

Each sample will be clearly labeled with a unique identifier, expiration date, analyte category or blank, appropriate safety warnings, and color-coded label on the jar.

Records related to the preparation of the samples for each sample set will be maintained

for the full five years. The records will contain the means of preparation, logbooks pertaining to the preparation of the spiking standards, identity and mass of the weighed samples, and the identity of the preparer.

Shipping containers, artificial ice, or any other shipping materials will be one-way in design and will not be returned or reused in any other set. Shipping containers, packaging, labeling, and methods will comply with all local, state, and federal codes. The test materials will be packaged and shipped by such means that the test materials will arrive at the laboratories in a condition suitable for analysis. The participants shall be notified of the expected sample arrival date in writing by fax, letter, or E-mail at least one (1) week prior to shipment. The participating labs may indicate to the contractor the intention to not participate in a set or not to analyze a particular sample by notifying the contractor prior to receipt of the samples. Cost of the shipment to the participant will be included in the cost of the program.

Each set shall include sufficient information, documentation, and any other materials needed for the participant to complete and submit the data from the set. This documentation shall at minimum include the participants ID, the due or postmark date for the completion of the test material round, the identity of the matrix being studied, the report material and any pertinent instruction or information required.

In the case of the reporting of the final results, all participants will remain anonymous and identified only by a code number. The code number shall be included with each set and on all documentation to the participant.

The participant shall have 45 calendar days to complete the set. The contractor shall identify the completion date in the documentation submitted with the sample set to the participant. Participants must submit all required information by the completion date or data will not be included in the final report.

The contractor will calculate and distribute reports from all sample sets within 30 days of the close of each sample set to the participating laboratories and EPA-BEAD. The reports will include summary data that includes the numerical results of all participants reported in a coded format. The contractor will also provide each participating laboratory and the EPA-BEAD the assigned value, z-score, and numerical result of each analyte of the sample set reported by the laboratory. The participating laboratories will establish their own protocols for evaluating the results. The contractor will present the data and z-scores but will make no judgment of its acceptability. The contractor will also report reference laboratory results for applicable analytes.

DELIVERABLES:

1) Draft written report including completed checklists on the results from each method review shall be submitted to the PO, APO, or WAM within the time frame specified in the Work Assignment.

2) Final written report evaluations incorporating any changes provided by the PO, APO, or WAM shall be submitted within the time frame specified in the Work Assignment.

ACCEPTANCE CRITERIA:

- The final reports shall be submitted within the time frame specified in the Work Assignment. The reports will include a completed checklist on the results from each sample set completed. The report will completely address all of the required objectives, issues, deliverables, and schedules as specified in the Work Assignment.

Task 3: Assist to Perform a Feasibility Study to Compile Information for the Development, Implementation, and Operation of a Web-Based Reporting System for State FIFRA Laboratories

The Contractor shall assist in the acquisition and compilation of information to be used in the preparation of a feasibility study for the development, implementation, and operation of a web-based reporting system of check sample/proficiency sample program for the state FIFRA laboratories. This will require reviews of a number of program elements including:

- the concentrations to be reported in the check sample/proficiency sample program by all participating state laboratories including precision and accuracy;
- the type of statistical methods and criteria for evaluating and reporting of the results of the individual state laboratory data including the z-scores and their incorporation into a final processed report;
- format of the final report;
- security controls that will be required for the receipt of state FIFRA laboratory

check sample/proficiency sample program data, maintenance of anonymity of each participating state laboratory, the state laboratory and EPA-BEAD accessibility to the final tabulated, processed individual laboratory and over-all data report, and maintenance of the data base for the length of the contract.

Work Approach

In gathering information, the contractor shall identify himself/herself as a contractor to EPA, not an EPA employee. The contractor shall not interpret EPA policy on behalf of EPA nor make decisions on matters of policy, regulation, or statute.

DELIVERABLES:

1) Prepare a draft report containing reviews of the program elements to be used in the feasibility study to compile information in the check sample/proficiency sample program for a secure web-based result analysis and reporting system. This assistance is strictly for the preparation of a feasibility study and not for any implementation of its conclusions. The report will be completed within the time frame specified in the Work Assignment. EPA will provide comments on the report within ten working days of receipt of the draft Compilation of Check Sample/Proficiency Sample Program Elements.

ACCEPTANCE CRITERIA:

The draft and final reports shall be submitted within the time frame specified in the Work Assignment.

5. PERFORMANCE REQUIREMENTS SUMMARY TABLE

Performance Requirement	Performance Standard	Method of Surveillance	Acceptable Quality Limit	Incentive/ Disincentive
General Requirements				
Draft and final reports under all tasks.	Reports shall be submitted within the time frame specified in the work assignment (WA).	EPA will document the date of receipt of each report.	85% of the draft and final reports submitted within the time frame specified in the WA.	Increase/reduce fix fee by no more than 1 percentage point based on biannual evaluations .
FIFRA State Laboratory Check/Proficiency Sample QA Program Support				
Develop & Implement Plans for Check Sample Exercise Program	Program addresses methods, procedures, and objectives outlined in the WA	EPA will review and approve check sample exercise plans. EPA will review reports to States on results of implementation.	Plans should address 100% of the methods & procedures.	Increase/reduce fixed fee by no more than 1 percentage point based on biannual evaluations .
Prepare Check Samples	Check samples prepared using established procedures and practices.	EPA will review all check sample reports, including stability and homogeneity testing.	95% of all check samples prepared completely and accurately within the time frame in the WA.	Increase/reduce fixed fee by no more than 1 percentage point based on biannual evaluations .
Implementation of Check Sample Program	Check samples will be shipped to the participating laboratory in accordance with plan and results may be analyzed, tabulated, and reported by web site.	EPA will review all check sample set reports and status of web site (if web site approach is adopted).	95% of all check sample set reports for completeness and accuracy within the time frame in the WA.	Increase/reduce fixed fee by no more than 1 percentage point based on biannual evaluations .

Preparation of Program Elements to be Use in a Feasibility Study for the Development, Implementation, and Operation of a Web-based Reporting System for All State Laboratories	Cost estimate addresses the procedures and objectives outlined in the WA	EPA will review the cost and funding of development and implementation of the web site.	Cost estimate should address 100% of the development and implementation procedures and statistics of the reporting system.	Reports shall be submitted within the time frame specified in the work assignment (WA).

APPENDIX A

Table 1 - Category and Analyte Concentration for Soil

Category and Analyte Concentration Range for Soil Samples	Chemical
Category (1) Glyphosate and Metabolite	Glyphosate
0.4 ppm to 2.0 ppm	Amino Methyl Phosphonic Acid (AMPA)

Category and Analyte Concentration Range for Soil Samples	Chemical
Category (2) Imidazilinones	Imazethapyr
0.05 to 0.20 ppm	Imazapyr
	Imazamox
	Imazaquin

Category and Analyte Concentration Range for Soil Samples	Chemical
Category (3) OP/ON	Acephate
0.10 to 2.0 ppm	Acetochlor
	Atrazine
	Chlorpyrifos
	Chlorothalanil
	Cyanazine
	Diazinon
	Demeton-O
	Demeton-S
	Dimethoate
	Ethion
	Fenthion
	Fonofos
	Malathion
	Methamidaphos
	Pendimethalin

	Parathion
	Parathion-Methyl
	Phorate
	Phosmet
	Propazine

Category and Analyte Concentration Range for Soil Samples	**Chemical**
Category (4) Herbicides	Aciflourfen
0.05 to 2.0 ppm	2,4-D
	Chloramben
	Clopyralid
	Dalapon
	Dicamba
	Dinoseb
	MCPA
	MCPP
	Pentachlophenol
	Picloram
	2,4,5-TP (Silvex)

Table 2 - Category and Analyte Concentration for Foliage

Category and Analyte Concentration Range for Foliage Samples	Chemical
Category (1) Glyphosate and Metabolite	Glyphosate
0.1 ppm to 200 ppm	Amino Methyl Phosphonic Acid (AMPA)

Category and Analyte Concentration Range for Foliage Samples	Chemical
Category (2) Imidazilinones	Imazethapyr
0.02 to 30 ppm	Imazapyr
	Imazamox
	Imazaquin

Category and Analyte Concentration Range for Foliage Samples	Chemical
Category (3) OP/ON	Acephate
0.05 to 100 ppm	Acetochlor
	Atrazine
	Chlorpyrifos
	Chlorothalanil
	Cyanazine
	Diazinon
	Demeton-O
	Demeton-S
	Dimethoate
	Ethion
	Fenthion
	Fonofos
	Malathion
	Methamidaphos

	Pendimethalin
	Parathion
	Parathion-Methyl
	Phorate
	Phosmet
	Propazine

Category and Analyte Concentration Range for Soil Samples	**Chemical**
Category (4) Herbicides	Aciflourfen
0.05 to 200 ppm	2,4-D
	Chloramben
	Clopyralid
	Dalapon
	Dicamba
	Dinoseb
	MCPA
	MCPP
	Pentachlophenol
	Picloram
	2,4,5-TP (Silvex)